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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,223	09/12/2003	Stephen D. Pacetti	50623.330	9127
<div>7590 12/28/2007</div> <div>Paul J. Meyer, Jr. Squire, Sanders & Dempsey L.L.P. Suite 300 1 Maritime Plaza San Francisco, CA 94111</div> <div>EXAMINER EDWARDS, LAURA ESTELLE</div> <div>ART UNIT PAPER NUMBER</div> <div>1792</div> <div>MAIL DATE DELIVERY MODE</div> <div>12/28/2007 PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/662,223

Applicant(s)

PACETTI ET AL.

Examiner

Laura Edwards

Art Unit

1792

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-7 and 25-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-7, and 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 4-7, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al (US 5,836,965) in view Helfrich (US 5,308,338) and Scanlon et al (US 2,845,346).

Jendersee et al teach a stent delivery device (i.e., catheter) or workholder for supporting the stent, the device comprising a tubular support member (36) for supporting the stent and a first cuff or retaining member (54) configured to contact one end of the stent with an outer stent support surface and a second cuff or retaining member (54) to make contact with another side of the stent with an outer stent support surface whereby the retaining members face one another in a side to side configuration and the retaining members can be made from any implantable material from stainless steel to polymers (see col. 7, lines 34-54). The Jendersee et al are silent concerning the retaining member(s) having a porosity to the extent of a closed pore system. However, it was known in the art, at the time the invention was made, to provide a catheter with cuffs made from porous implantable materials from polymers to sintered metal and ceramics as evidenced by Helfrich (see col. 4, lines 31-39). It was further known in the sintered metal composite art, to enable sintered metal bodies to be made of a closed pore construction as evidenced by Scanlon et al (see col. 1, lines 15-23). In light of the teachings of Jendersee et al that any implantable material can be used to make the retaining member(s), the teaching of Helfrich with respect to catheters having cuffs made from porous material (i.e., sintered metal), and the teaching of Seanlon et al, that sintered metal while porous, can be made to have a closed

pore system, one of ordinary skill in the art would have found it obvious to make the retaining member(s) of any appropriate porous and/or non-porous implantable material so as to retain the stent on the catheter, the catheter with the stent thereon to be used in or out of the body. Furthermore, it would have been obvious to one of ordinary skill in the art to utilize any appropriate porous or nonporous implantable material from which to make the retaining member(s), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Acknowledgement is made of Applicants' use of the claimed apparatus for coating the stent, however, the intended use of the apparatus has been given no patentable weight without the positive recitation in the body of the claim of the structure or means for effecting coating of the stent.

With respect to the pore size, it is within the level of ordinary skill in the art to determine, via routine experimentation, the appropriate pore size including diameter of the material used to make the closed pore retaining member(s).

Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jendersee et al (US 5,836,965) in view Helfrich (US 5,308,338).

Jendersee et al teach a stent delivery device (i.e., catheter) or workholder for supporting the stent, the device comprising a tubular support member (36) for supporting the stent, a first cuff or retaining member (54) configured to contact one end of the stent and a second cuff or retaining member (54) to make contact with another side of the stent whereby the retaining members can be made from any implantable material from stainless steel to polymers (see col. 7,

lines 34-54). Jendersee et al are silent concerning the cuff(s) or retaining member(s) having a porous layer thereon capable of absorbing or at least partially absorbing a fluid. However, it was known in the medical art, at the time the invention was made, to provide a catheter with cuffs made from porous implantable materials (i. e., polymers to sintered metal and ceramics) to promote ingrowth of tissue as evidenced by Helfrich (see col. 4, lines 31-39). It would have been obvious to one of ordinary skill in the art to make the cuff(s) or retaining member(s) of a porous layer material as taught by Helfrich in the device of Jendersee et al in order to enable the absorption or retention of fluid when the stent is pretreated or enable tissue growth when the device is implanted. Furthermore, it would have been obvious to one of ordinary skill in the art to utilize any appropriate porous or nonporous implantable material from which to make the retaining member(s), since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Acknowledgement is made of Applicants' use of the claimed apparatus for coating the stent, however, the intended use of the apparatus has been given no patentable weight without the positive recitation in the body of the claim of the structure or means for effecting coating of the stent.

With respect to the first and second elements or cuffs or retaining members being capable of movement closer or further apart, the retaining members or cuffs are placed on a workholder or catheter and moved together or further apart until the desired location of the retaining members or cuffs are affixed or attach via conventional means to support the stent on the workholder or catheter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nadine Norton can be reached on (571) 272-1465. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Laura Edwards
Primary Examiner
Art Unit 1792

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December 23, 2007